**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF PENNSYLVANIA**

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| PFIZER INC.,<br><br>Plaintiff,<br><br>v.<br><br>JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.,<br><br>Defendants. | Civil Action No. 2:17-cv-04180-JCJ |

**PFIZER INC.'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

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## INTRODUCTION

Pfizer commenced this action to challenge the scheme of Defendants Johnson & Johnson and Janssen (collectively, J&J) to maintain a monopoly by shielding their biologic drug, Remicade, from competition principally through a web of exclusive dealing contracts. J&J's scheme has led to the near-total foreclosure of competition from FDA-approved "biosimilars," including Pfizer's biosimilar, Inflectra. The result of that foreclosure has been higher prices and reduced choices for consumers—exactly the harms that the antitrust laws are intended to prevent. Through its motion to dismiss, J&J seeks to avoid any scrutiny of its conduct by arguing that its exclusive dealing contracts should be viewed as good for consumers and that Pfizer could have had more success against J&J's exclusionary actions if it had employed a different business strategy. Those arguments have no merit, especially on a motion to dismiss where the Court must accept as true Pfizer's well-pleaded allegations—not J&J's efforts to spin the facts, and indeed to distort the allegations of Pfizer's Complaint.

J&J does not dispute that the Complaint adequately alleges that:

- for nearly twenty years, J&J has maintained monopoly power over properly defined antitrust markets (¶¶ 3, 80-101);
- over the past decade, J&J has used its monopoly power to raise the price of Remicade by more than 62 percent (¶ 81);
- faced with the prospect of competition from Inflectra, J&J entered into exclusive dealing contracts with health insurers that require an explicit commitment not to cover Inflectra or to do so only under circumstances so rare that they are practically non-existent (¶¶ 55-64);
- if insurers decline to accept these contractual exclusivity requirements, J&J threatens to impose substantial financial penalties by raising the price for Remicade *and* by raising prices of other drugs that J&J offers but Pfizer does not (¶¶ 55-67);

- J&J employs the same exclusionary contracting strategies with respect to certain healthcare providers (e.g., clinics, hospitals, and the like) that buy and administer the drugs at issue, which must be administered by a healthcare professional (¶¶ 73-79);

- J&J's exclusionary contracts foreclose more than 70% of all commercially insured patients in the United States from access to Inflectra, and more than 90% of healthcare provider accounts have refused to stock Inflectra at all in the face of the widespread coverage gaps J&J itself engineered with its contracts (¶¶ 8, 10, 12, 59, 72, 79, 100, 102, 127).

These allegations, which are supported by an immense amount of factual detail in the Complaint, are more than enough to sustain an antitrust claim at the pleading stage. J&J does not take issue with the sufficiency of *any* of them. Instead, J&J makes two arguments for dismissal. First, it argues that to state a claim against J&J for engaging in anticompetitive conduct, Pfizer was required to allege that it tried to compete by offering its own multi-product "bundled" discounts. No case, from any court, has ever established such a pleading requirement. And, not only is the rule that J&J proposes unprecedented, it fundamentally mischaracterizes Pfizer's claim and ignores the allegations of the Complaint. To be sure, multi-product bundling is *one* form of exclusionary conduct that J&J has employed to thwart competition from Inflectra, but it is clearly not the *only* or even the central conduct alleged, as J&J tries to suggest.

J&J ignores altogether the centerpiece of the exclusionary scheme that Pfizer alleges: the *contractual exclusivity* in J&J's contracts with insurers, which requires them to deny coverage to Inflectra, thus (a) foreclosing Inflectra from reaching more than 70% of commercially insured patients nationally and (b) leading more than 90% of healthcare provider accounts in the country to decline to purchase Inflectra altogether in the face of such widespread coverage gaps. In effect, J&J's argument asks the Court to reject the principal factual allegation in Pfizer's Complaint—that Inflectra's

foreclosure is the result of J&J's exclusive insurer-level contracts—and to accept instead J&J's bald speculation that if Pfizer had adopted a different contracting strategy (by bundling Inflectra with some other, unidentified products) then perhaps insurers would not have entered into exclusive contracts with J&J in the first place. If that is how J&J wants to try to defend against these claims, it can try to prove its theory at the summary judgment stage or at trial. Such arguments cannot be entertained on a motion to dismiss.

J&J's second argument—that Pfizer did not adequately allege that its own prices were lower than J&J's—is also meritless. The Complaint's allegations about price are clear: Pfizer set the initial list price (often referred to as Wholesale Acquisition Cost or "WAC") for Inflectra at 15% below the list price for Remicade and it offered substantial discounts, rebates and other concessions with the purpose and effect that the per-unit net price for Inflectra would be lower than that for Remicade (Compl. ¶¶ 13, 46, 65, 76, 103); and, as of September 2017 (when the complaint was filed), the government-published "average selling price" (or "ASP") for Remicade, a price reflecting discounts, rebates, and other price concessions, was more than 10% higher than that of Inflectra, having increased since the time of Inflectra's launch while Inflectra's ASP decreased over the same period. *Id*. ¶¶ 13, 40, 65, 81-82, 104, 112. The fact that J&J has been able to maintain higher prices, while preventing Inflectra from gaining a foothold in the relevant market and maintaining more than 96% of infliximab sales, demonstrates the anticompetitive effects of its exclusionary scheme.

J&J tries to muddy the waters by arguing that *neither* of the two publicly available measures (WAC or ASP) accurately reflects its pricing. That is, at best, a fact-bound defense that will need to be tested in discovery. There is no reason why, at the

motion to dismiss stage, the Court should credit J&J's assertion that despite Pfizer's allegations and publicly available information indicating that Remicade is more expensive than Inflectra, in reality the opposite is true. Indeed, J&J cannot even get its own story straight as to *why* it contends that Pfizer's allegations and the publicly available pricing data should not be believed—making one argument in its original motion to dismiss (i.e., that insurer rebates, a core issue in Pfizer's allegations, are not included in ASP) and then retracting it a week later in a "corrected" motion.

In any event, J&J's argument that Pfizer's price was not low enough misses the point. The Complaint alleges that J&J, a longstanding monopolist with over 96% market share and leverage over a broad "incontestable" segment of patients, conditioned the discounts and rebates it offered to insurers and healthcare providers on their contractual commitment to deal exclusively with Remicade, as part of an anticompetitive scheme designed to block Inflectra from gaining a foothold in the market. As a result, Inflectra has been foreclosed from competing for an overwhelming majority of commercially insured patients *regardless* of its price. J&J cites not a single case involving even remotely similar allegations that was dismissed at the pleading stage. J&J's motion should be denied.

## PFIZER'S COMPLAINT

Pfizer's Complaint sets forth in substantial detail J&J's multifaceted scheme to block biosimilar competition and maintain a monopoly for its blockbuster biologic Remicade. We outline below some of the key allegations supporting Pfizer's claims.

## I. Background

Biologics are medications derived from living organisms. Compl. ¶¶ 1, 28. A biosimilar is a version of a biologic that the FDA has found to have "no clinically meaningful differences" to the reference (or "originator") biologic in terms of safety, purity, and potency. *Id.* ¶¶ 4, 33. In 2010, Congress passed the Biologics Price Competition and Innovation Act ("BPCIA"), to promote price competition among biologics after the originator firm's patent protection has expired. *Id.* ¶¶ 1, 4, 31-32.

Although there are no clinically meaningful differences, biosimilars cannot be substituted for the reference biologic under state substitution laws without physician approval. *Id.* ¶¶ 30, 34. Thus, originator biologics used for chronic conditions enjoy an "installed base" of patients already stabilized on the originator who are not likely to switch even to a lower-priced biosimilar—and a key factor of competition for biosimilars is therefore new patients. *Id.* ¶¶ 9, 65-66. On average, about 70% of patients for biologics such as infliximab in any given year are legacy patients and 30% are new patients. *Id.* ¶ 74.

## II. Pfizer Introduces Inflectra into a Market Over Which J&J Had Exercised Monopoly Power for Nearly Twenty Years

J&J began selling Remicade in the United States in 1998, and it became J&J's best-selling drug by far, generating about $4.8 billion in U.S. sales in 2016 alone. *Id.* ¶ 3. Remicade is an infusion-administered product, meaning it is administered intravenously, and is used to treat various chronic conditions, including Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. *Id.* ¶¶ 35, 37, 38, 83.

Until November 2016, J&J had been the sole supplier of infliximab in the United States, meaning that J&J enjoyed approximately eighteen years of exclusivity for its product. *Id*. ¶¶ 5, 19, 20. Remicade thus has long enjoyed monopoly power in respect of infusion-administered therapies for the ailments it treats as well as over the "molecule" itself. *Id.* ¶¶ 80-97. In 2016, however, Pfizer introduced Inflectra, a biosimilar to Remicade. *Id*. ¶ 19. Inflectra was approved by the FDA in April 2016 and came to market in November 2016. *Id*. ¶¶ 5, 19.

**III. J&J's Exclusionary Conduct**

In response to the entry of biosimilar competition, J&J hatched a multifaceted scheme (which it labeled its "Biosimilars Readiness Plan") to preserve its monopoly on Remicade and ensure infliximab biosimilars would never become viable competitors. *Id*. ¶¶ 3, 55. J&J's scheme impacted multiple levels of the distribution chain, targeting both insurers and healthcare providers, and involved exclusive deals for Remicade, multi-product bundled rebates, rebates based on the bundling of new and existing patients, and a "rebate trap" that prevented Pfizer from gaining business no matter how far it lowered Inflectra's price. *Id.* ¶¶ 8, 9, 11, 55-79, 98.

***Exclusive contracts with health insurers.*** J&J induced insurers to enter into contracts that either (a) required the insurers to exclude Inflectra, and any other infliximab biosimilar, from reimbursement altogether or (b) applied a medically inappropriate "fail first" policy under which a patient would be required to fail on Remicade before trying its biosimilar Inflectra. *Id*. ¶¶ 8, 58. Such "fail first" conditions defy sound medical judgment because a physician would never treat a patient with Inflectra after the patient first fails on Remicade—Inflectra, after all, has been found by

FDA to have "no clinically meaningful differences" with Remicade.[1] *Id.* ¶ 71. Agreements containing such conditions thus have the same effect in practice as those requiring total exclusivity. *Id.* These exclusive contracts have foreclosed Inflectra's ability to vie for at least 70% of commercially insured patients in the United States. *Id.* ¶¶ 8, 59.

***Exclusionary rebates and bundling arrangements with health insurers.*** J&J has coerced insurers into these agreements by increasing its list price of Remicade and then threatening to deny insurers rebates for *all* existing Remicade patients (approximately 70% of patients overall) unless they agree to block usage of Inflectra. *Id.* ¶¶ 9, 66. J&J's denial of rebates serves as a substantial financial penalty for insurers that decline J&J's exclusivity commitments. *Id.* ¶ 9.

The financial penalty from J&J's "all-or-nothing" rebates is particularly effective because of the substantial "installed base" of existing patients across the country already stable on Remicade who are "highly unlikely" to switch to a biosimilar. *Id.* ¶¶ 9, 65. Thus, the demand for existing Remicade patients is economically incontestable, i.e., biosimilar firms cannot realistically compete for these patients. *Id.* J&J leverages this "incontestable" segment of patients (over which it has control as discussed above) to also control the "contestable" universe—new infliximab patients (approximately 30%)—by threatening to deny rebates on *all* Remicade prescriptions if *any* biosimilar prescriptions are reimbursed. *Id.* ¶¶ 9, 66. Industry observers have termed this the "rebate trap." *Id.* ¶ 66. To break the rebate trap, the biosimilar must either convert existing patients beyond

[1] *See also* Compl. ¶ 58 n.19 (noting that medical professionals have recommended against switching to the biosimilar where a patient has first failed on the originator product).

the "contestable" universe (which is not feasible), or extend insurer rebates that at least equal the dollar value of the rebates the originator would have paid—which in many cases would require pricing below marginal cost. *Id.* ("Even if Pfizer offers a significantly lower price for Inflectra unit-for-unit, as it has done, insurers will agree to J&J's exclusive deals to avoid losing rebates on the substantial base of existing Remicade patients[.]"); *see also id.* ¶ 77 ("For Pfizer to make up the J&J rebates/discounts that insurers and providers would lose on their existing Remicade patients, Pfizer would have to price Inflectra below its own average variable cost.").

J&J enhances the exclusionary power of these exclusive dealing contracts by bundling rebates on multiple different products such that insurers that refuse to grant exclusivity to Remicade would pay higher prices and forego enhanced rebates on J&J products beyond Remicade. *Id.* ¶¶ 9, 67. The net effect of these exclusionary practices is that the insurers subject to them have no real choice but to accept J&J's exclusivity conditions. *Id.* ¶¶ 9, 68. As noted, J&J does not challenge the adequacy of any of these factual allegations.

***J&J-engineered coverage restrictions impact provider purchasing, further magnifying Inflectra's foreclosure from the market.*** Inflectra's exclusion from coverage by most commercial insurers, as a result of J&J's contracts, has a spillover effect on healthcare providers' purchasing decisions, causing them to not stock Inflectra at all because they are uncertain whether they will be reimbursed after using it. *Id.* ¶¶ 10, 69, 70, 71. As infliximab is an infusion product, medical providers (e.g., clinics, hospitals and the like) must purchase infliximab at their own cost for administration to patients—in contrast to self-administered drugs for which the physician writes a

prescription and the patient obtains the drug at a retail pharmacy. *Id*. ¶¶ 49-50. Accordingly, providers are very focused on insurance coverage of such products, and will not stock a product unless they are confident that it will be reimbursable by insurance. *Id*. ¶¶ 8, 10, 48, 50-51. Uncertainty over Inflectra's coverage—engineered by J&J through its exclusionary scheme—has caused providers to overwhelmingly choose to stock *only* Remicade rather than risk possibly being denied coverage for Inflectra. *Id*. ¶¶ 10, 69, 71. As a result, the effective foreclosure caused by J&J's conduct is expanded well beyond the *70%* of commercially insured patients. *Id*. ¶¶ 10, 72. As of September 1, 2017, about *90%* of healthcare provider accounts had purchased *no Inflectra*. *Id*. ¶¶ 10, 12, 72, 79.

***Exclusionary rebates and bundling arrangements with healthcare providers.*** To amplify Inflectra's foreclosure further, J&J extended its restrictive contracts to certain selected healthcare providers. Compl. ¶¶ 11, 73. After Inflectra's introduction, J&J began offering certain large providers additional rebates and/or discounts on Remicade, but *only if* the provider committed to Remicade over Inflectra. *Id*. ¶ 74. To obtain such rebates and discounts, J&J requires providers to maintain purchase levels for Remicade very close to those of the year *before* Inflectra's launch, when Remicade was the *only* infliximab option—in effect requiring providers to exclusively use Remicade for new patients. *Id*. Additionally, J&J has used multi-product bundling in its provider contracts as yet another tactic in its anticompetitive scheme. *Id*. ¶ 75. Conditioning rebates linked to other J&J products upon promises not to do business with Inflectra compounds Inflectra's exclusion. *Id*.

## IV. Pfizer's Efforts to Compete And Its Inability to Break Anticompetitive Barriers Created by J&J

The Complaint includes detailed allegations regarding how Pfizer has vigorously attempted to compete with J&J, including the following:

- ***Inflectra's list price was lower than Remicade's.*** The Complaint alleges that upon launch, Pfizer set Inflectra's list price at 15% below Remicade's list price. *Id*. ¶¶ 5, 46. Given J&J's subsequent list price increases for Remicade, that difference has only increased. *See id.* ¶ 13.

- ***Pfizer offered substantial additional discounts and rebates from Inflectra's list price to insurers and providers.*** Pfizer then "offered substantial additional pricing concessions" to insurers and providers, in some instances more than 40% below Inflectra's already lower list price. *Id*. ¶ 46.

- ***The goal and effect of Pfizer's efforts was to price Inflectra lower than Remicade unit-for-unit.*** Pfizer further offered "guarantees that Inflectra would be less expensive unit-for-unit than Remicade," *id.* ¶ 103, both to insurers and providers. *Id.* ¶ 46 ("[I]ndeed, for many customers, Pfizer committed to ensure that Inflectra would have a lower net per-unit price than Remicade."), 76 ("Pfizer was and is prepared to negotiate with providers to make Inflectra the lower-priced infliximab option on a per-unit basis, and has even offered to guarantee that Inflectra would be less expensive unit-for-unit than Remicade."); *see also id.* ¶¶ 47, 64, 66, 76.

- ***Inflectra's ASP was lower than Remicade's.*** The result of these efforts was that, as the Complaint alleges, Pfizer "was charging a lower price for Inflectra than J&J was charging for Remicade." *Id.* ¶ 47. This lower price is reflected in the ASPs for Inflectra and Remicade, which as noted include discounts and rebates offered to insurers and providers. *Id.* ¶¶ 65, 104. As of September 2017, Remicade's ASP was more than 10% higher than Inflectra's ASP. *Id*. ¶ 13.

The Complaint also includes detailed allegations regarding how J&J's exclusionary contracting ensures that even Pfizer's aggressive competitive offers cannot succeed unless it prices Inflectra below its cost. *See, e.g.*, *id.* ¶ 77. Indeed, the Complaint explains that when the total amount of discounts that J&J offers insurers and providers, including their multi-product bundling discounts, is attributed to the contestable portion of Remicade sales, "J&J is pricing Remicade below its own average variable cost." *Id.* ¶¶ 78, 113, 121, 139. And the Complaint explains why the rebate trap works and why

Pfizer cannot meaningfully compete against it: providers and insurers "are the gateway" for access to patients, and there are "no viable alternative means of distribution or sale." *Id.* ¶ 128. "Biosimilar competitors to J&J have no practical alternative means of selling infliximab to patients." *Id.* Finally, the Complaint explains how J&J's bundling compounds the exclusionary effect of its conduct, as Pfizer does not have products that compete with the J&J products that Pfizer is aware of being bundled. *See, e.g., id.* ¶ 67.

## V. J&J's Exclusionary Contracting Scheme Has Caused Harm to Competition

As a result of J&J's exclusionary contracting scheme and despite Pfizer's efforts to compete, prices are increasing, biosimilar competition is being foreclosed, and J&J has maintained its monopoly power. *Id.* ¶¶ 8, 12, 47, 80-82, 100, 102. J&J tries to depict itself as offering price competition by entering into the exclusionary contracts at the heart of Pfizer's Complaint. But, the Complaint alleges that the net result of those contracts has been *higher* prices, not lower prices, for purchasers. *Id.* ¶¶ 13, 15, 104.

Despite the "discounts and rebates" J&J supposedly offers through its contracts with insurers and providers (*see* Defs.' Corrected Mem. at 2, ECF No. 31), Remicade's list price has gone up, not down, since Inflectra entered the market. That price increase is no mere coincidence, nor is it a fact that can be simply brushed aside (as J&J tries to do in its motion) because it concerns "only" the list price for Remicade. As Pfizer explains in its Complaint, Remicade's list price functions as a penalty price that insurers or providers must pay if they fail to deal exclusively with J&J; thus, by increasing the list price, J&J increased the threatened penalty for insurers or providers that did not accept its exclusivity requirements.[2] Compl. ¶¶ 9, 13, 64.

[2] J&J had followed a regular pattern of twice-a-year WAC increases for years and did not deviate after Inflectra entered—*until* Pfizer filed this lawsuit. J&J did not take a list price

Furthermore, it is not only the list price for Remicade that has gone up. Government-published ASP data for Remicade reflects that Remicade's average selling prices, net of rebates, discounts, and other price concessions, has increased, despite the presence of lower-priced biosimilar competition. *Id.* ¶¶ 81-82. As of September 2017, nearly a year after Inflectra's launch, Remicade's ASP was more than 10% higher than Inflectra's. *Id.* ¶ 13. As the published ASP data show, Remicade's ASP increased after Inflectra's entry, whereas Inflectra's ASP was always lower than Remicade's (and decreased). *Id.* ¶¶ 13, 81-82, 104, 112.

J&J's exclusionary scheme has led to the near total foreclosure of Inflectra and deprived consumers of the benefits of competition. *Id.* ¶ 102-03. Despite increasing its prices, J&J has maintained Remicade's monopoly position with over 96% share of infliximab unit sales in the United States as of September 2017. *Id.* ¶¶ 12, 47, 82, 100, 102. More than 90% of provider accounts had not even stocked Inflectra. *Id.* ¶ 12. J&J's conduct, if it continues, will dampen biosimilar developers' incentives to invest in bringing biosimilars to market, *id.* ¶ 103, and continue to injure insurers and patients who are bearing the burden of supracompetitive healthcare costs for infliximab and being deprived of the choice to use biosimilars. *Id.* ¶¶ 13, 104.

J&J's effort to portray its exclusive dealing contracts as a boon to consumers and competition, and Pfizer's antitrust claims as merely one competitor's "sour grapes," is thus directly at odds with the facts as alleged in the Complaint. That effort also is belied by the fact that since Pfizer filed this lawsuit, six separate actions have been filed on behalf of classes of patients and insurers/payers of Remicade—the

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increase in the Fall of 2017, which was the first time that Remicade's WAC remained steady since at least 1999. Pfizer filed its lawsuit on September 20, 2017.

very constituents that J&J contends benefited from its contracts—alleging consumer harm arising from J&J's conduct.

**J&J'S MOTION TO DISMISS**

J&J filed its motion to dismiss, together with its initial memorandum in support thereof, on November 28, 2017. J&J did not (and does not) challenge the sufficiency of the Complaint's allegations concerning J&J's anticompetitive scheme, including that J&J is a long-standing monopolist in properly defined antitrust markets; that in response to the entry of biosimilar competition, J&J leveraged its control over its massive universe of legacy Remicade patients to extract exclusive agreements from major insurers and certain providers; that these agreements, together with J&J's leverage of coverage gaps created by the contracts it negotiated, have allowed J&J to raise the price of Remicade and still maintain a monopoly after a year of competition from biosimilar products; that J&J's exclusionary contracts foreclose more than 70% of all commercially insured patients in the United States from using Inflectra; and that 90% of healthcare provider accounts have declined to stock Inflectra at all in the face of coverage gaps engineered by J&J's contracts. In short, J&J does not dispute that Pfizer has alleged that J&J's scheme has led to infliximab biosimilars being foreclosed from nearly the entire commercial insurer and provider channels—the only avenues by which an infusion product such as infliximab can reach patients.[3] Compl. ¶¶ 49, 50, 53, 79, 100. In fact, J&J touts the success of its scheme in public statements. *Id.* ¶¶ 14, 82.

[3] J&J notes that there are other drug products (including Humira and Enbrel) used for some of the same ailments that infliximab treats, Defs.' Corrected Mem. at 6, but J&J has not sought dismissal based on any alleged shortcoming in Pfizer's market definition or monopoly power allegations. In any event, the Complaint details key reasons why such self-administered products are not properly included in the product markets defined in the Complaint, including that these other products are not reasonable substitutes and "a small

Rather than contesting Pfizer's pleading on any aspect of its wrongdoing, J&J asserted that the Complaint nonetheless fails to allege antitrust injury because, according to J&J, the Complaint does not plead enough detail that Pfizer could not have defeated J&J's scheme with multi-product bundles of its own and/or that Pfizer, in fact, priced Inflectra lower than Remicade. Defs.' Corrected Mem. at 16-18. As detailed below, J&J is wrong—both on what must be alleged to support antitrust injury in light of the wrongdoing Pfizer actually asserts and about what Pfizer actually alleged as to bundling and pricing. *See infra* Sections I-III.

On December 4, 2017, J&J filed a "corrected" memorandum in which it was forced to retract a main argument it had advanced regarding the supposed exclusion of insurer rebates from government-published ASP—an argument it relied upon heavily to suggest that Pfizer had not plausibly alleged that Inflectra's net prices (i.e., prices net of insurer rebates and other discounts) were lower than Remicade's. Defs.' Mem. at 3-4,

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but significant non-transitory" increase in the price of infliximab would not cause substitution to these other products. Compl. ¶¶ 86-88, 92, 94-96; *see also, e.g.*, *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 315 (3d Cir. 2007) (plaintiff adequately alleged a relevant market by focusing on allegations regarding lack of "interchangeab[ility] . . . or substitutab[ility]"); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 712-13 (E.D. Pa. 2014) (plaintiffs adequately alleged relevant market by "referenc[ing] the rules of reasonable interchangeability and cross-elasticity of demand . . . and [] plausibly explain[ing] why other similar products do not fall within the relevant market" by describing distinctions in the practical applications between Suboxone and its generics, and other drugs). And, market definition typically is not an issue that should be resolved on a motion to dismiss. *See, e.g.*, *Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 482 (1992) ("The proper market definition in this case can be determined only after a factual inquiry into the commercial realities faced by consumers."); *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 183 (3d Cir. 2015) ("'[I]n most cases, proper market definition can be determined only after a factual inquiry into the commercial realities faced by consumers.'"); *Bansavich v. McLane Co.*, 2008 U.S. Dist. LEXIS 89071, at *6-7 (D. Conn. Oct. 31, 2008) ("On a motion to dismiss, the Court need not engage in extensive analyses of reasonable interchangeability and cross elasticity of demand.").

7-8, 16. As J&J stated in its initial memorandum: "as Pfizer is well aware . . . the [ASP] reported by the government [does] not take into account rebates or discounts to payors [*i.e.* health insurers] who reimburse the providers. Consequently, [according to J&J,] Inflectra's and Remicade's . . . ASPs do not disclose whether the net price of Inflectra to payors is higher or lower than the net price of Remicade." Defs.' Mem. at 3-4.

But Pfizer's allegation that ASP incorporates rebates to both insurers and providers was (and is) correct, as J&J was forced to concede in its December 4, 2017 submission, admitting that it had not "accurately describe[d] how [ASP] . . . can be calculated." Cover Letter to Defs.' Corrected Mem. Thus, J&J cannot claim that the "all-or-nothing" rebates it has used to secure exclusivity commitments from insurers and providers have led to lower aggregate prices for Remicade; on the contrary, due to the concomitant list price increases J&J has imposed since biosimilar competition entered, overall prices for Remicade have instead gone up. Indeed, Pfizer's Complaint points out numerous times that since biosimilar entry, (a) Remicade's ASP has been *increasing*, not decreasing as one might expect upon the entry of a new competitor (Compl. ¶¶ 13, 82, 104, 112, 120, 138), and (b) Inflectra's ASP has been lower (10% lower than Remicade's as of September 2017) and *decreasing*. *See, e.g.*, Compl. ¶¶ 13, 40, 65, 81-82, 104, 112. Nor can J&J avoid that, in aggregate, Pfizer's net per-unit prices for Inflectra, not just its list prices, have been lower than Remicade's.

Above all, J&J's December 4 retraction underscores that its arguments regarding price are quite clearly factual disputes that cannot be resolved on a motion to dismiss and reinforces that J&J's motion should be denied. J&J has offered no reason why the Court should not accept as true Pfizer's numerous detailed factual allegations

regarding both its own pricing and net pricing trends for Remicade and Inflectra which, as further discussed below, lend additional plausibility to Pfizer's allegations relating to antitrust injury.

**LEGAL STANDARD**

A complaint need only contain "enough factual matter (taken as true) to suggest . . . that discovery will reveal evidence" of the conduct averred. *Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 177 (3d Cir. 2010) (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008)); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). "[T]he question is not whether plaintiffs will prevail at trial, but whether they should be given an opportunity to offer evidence in support of their claims." *In re Hypodermic Prods. Antitrust Litig.*, 2007 U.S. Dist. LEXIS 47438, at *18 (D.N.J. June 19, 2007). Pleadings "do not require heightened fact pleading of specifics" and need only include "enough facts to state a claim to relief that is plausible on its face." *RAH Color Techs. LLC v. Ricoh USA, Inc.*, 194 F. Supp. 3d 346, 348 (E.D. Pa. 2016) (J. Joyner) (quoting *Twombly*, 550 U.S. at 570). Inferences must be resolved in plaintiff's favor on a motion to dismiss. *See, e.g.*, *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 786 n.2 (3d Cir. 2016); *Phillips*, 515 F.3d at 228.

"[I]t is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases." *W. Penn Allegheny Health Sys. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010); *see also, e.g.*, *In re Hypodermic Prods. Antitrust Litig.*, 2007 U.S. Dist. LEXIS 47438, at *42 (complaint provided defendant "adequate notice of the particular grounds upon which plaintiffs' claims rest, particularly given the fact that plaintiffs have not yet had the benefit of discovery").

## ARGUMENT

Pfizer asserts four causes of action based on a multifaceted scheme—consisting principally of exclusive contracting, and augmented by multi-product bundling—to foreclose newly entering biosimilar competitors from meaningfully competing with Remicade for the business of both healthcare insurers and providers. As detailed in the Complaint, J&J's scheme violates Sections 1 and 2 of the Sherman Act and Section 3 of the Clayton Act. Compl. Counts I-IV; *see also, e.g.*, *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 269 n.9 (3d Cir. 2012) ("Exclusive dealing claims may be brought under Sections 1 and 2 of the Sherman Act and Section 3 of the Clayton Act.").

J&J states that "[t]he law applicable to Pfizer's Section 1 and Section 2 claims under the Sherman Act and its Section 3 claim under the Clayton Act is effectively the same," and notes that "[a]mong other elements of its claims, Pfizer must plead facts showing that [J&J] engaged in anticompetitive conduct and that Pfizer suffered antitrust injury as a result." Defs.' Corrected Mem. at 9. J&J does not dispute that Pfizer has met its burden to plead facts showing that J&J engaged in anticompetitive conduct—as discussed, the Complaint describes in detail J&J's anticompetitive scheme to block biosimilar competition through a web of exclusionary contracts with insurers and healthcare providers. Nor does J&J dispute Pfizer has sufficiently pled other key elements of its antitrust claims, including that J&J had monopoly power in a properly defined antitrust market and that J&J's exclusionary contracts foreclosed competition from a substantial part of the relevant market.

The *only* element of Pfizer's antitrust claims that J&J argues that the Complaint does not satisfy is antitrust injury. In order to establish that it suffered an antitrust injury, a plaintiff must show that its harm "stems from a competition-*reducing*

aspect or effect of the defendant's behavior." *Atl. Richfield Co. v. U.S. Petroleum Co.*, 495 U.S. 328, 344 (1990) (original emphasis). Furthermore, "[t]he existence of antitrust injury is not typically resolved through motions to dismiss." *Xtreme Caged Combat v. Cage Fury Fighting Championships*, 2015 U.S. Dist. LEXIS 69796, at *7-8 (E.D. Pa. May 29, 2015). J&J's arguments that Pfizer failed to plead the existence of antitrust injury here fail for the reasons set forth below.

## I. Pfizer Was Not Required to Allege an Inability to Employ Its Own Multi-Product Bundles

J&J first contends that Pfizer's Complaint should be dismissed because it "never alleges that [Pfizer] is incapable of offering competitive bundled discounts across its product lines." Defs.' Corrected Mem. at 12. J&J argues that due to this purported pleading failure, Pfizer cannot show that "it has suffered antitrust injury due to [J&J's] conduct or that lower prices resulting from Janssen's bundled discounts and rebates have resulted in harm to competition." *Id*. at 16. J&J thus asks this Court to rule on the pleadings that J&J's contracts *in fact* were examples of price competition, and that the harm Pfizer suffered *in fact* was self-inflicted (due to a lack of competitive effort), and therefore not cognizable under the antitrust laws. This effort fails for three reasons: (a) it is premised on a mischaracterization of Pfizer's Complaint, (b) Pfizer's pleading is more than adequate even if J&J's mischaracterization were accepted; and (c) J&J's proposal would require the Court to resolve pleaded facts in the absence of any factual record.

### A. J&J Mischaracterizes Pfizer's Complaint

The Court need not determine whether J&J's bundling practices, standing alone, caused Pfizer to suffer an antitrust injury. That is because J&J's attack on Pfizer's multi-product bundling allegations ignores the central allegations in Pfizer's Complaint.

In its Corrected Memorandum, J&J variously describes Pfizer's Complaint as a "bundling" case, *see, e.g.*, Defs.' Corrected Mem. at 12-13, and/or a challenge to J&J's "discounts and rebates," *see, e.g.*, *id.* at 2. These are attempts at misdirection as neither characterization comes close to fully depicting the multifaceted scheme Pfizer in fact alleges. *See supra* pp. 6-9. As the Complaint makes clear, "[a] *centerpiece* of J&J's strategy to block competition from biosimilars has been to secure contractual commitments from commercial insurance companies to exclude biosimilars from coverage under their plans, making *Remicade the exclusive infliximab available to patients* covered by those plans." Compl. ¶ 58 (emphasis added); *see also, e.g.*, *id.* ¶¶ 56, 59, 61-64, 73-75, 79. J&J ignores these allegations entirely: it does not mention "exclusive dealing" even once in its original or corrected memoranda.

Pfizer does allege that J&J engaged in conduct beyond its exclusionary contracting, including anticompetitive bundling, in order to amplify the anticompetitive effects of its exclusionary contracts. Compl. ¶¶ 9, 65-68. Bundling was yet one more tactic used by J&J in its anticompetitive, exclusionary scheme, but certainly not the only one. And J&J cannot evade Pfizer's Complaint by trying to conjure pleading deficiencies as to ancillary facets of the alleged scheme. The Third Circuit has made clear that "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's, Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003) (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)); *see also, e.g.*, *id.* ("[I]t would not be proper to focus on specific individual acts of an accused monopolist while refusing to consider their overall combined effect . . . We are dealing with what has been called the 'synergistic effect' of the mixture of the elements.") (citing

*City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992)); *City of Mishawaka v. Am. Elec. Power Co.*, 616 F.2d 976, 986 (7th Cir. 1980) ("It is the mix of various ingredients . . . in a monopoly broth that produces the unsavory flavor.").

Applying this standard, courts routinely deny motions to dismiss where the defendant focuses on isolated aspects of the claimed anticompetitive conduct rather than the overall conduct, taken as a whole. *See, e.g.*, *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 428 (D. Del. 2006) (denying motion to dismiss, rejecting attempt to isolate individual acts: "Plaintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not."); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 528 (D.N.J. 2004) (denying motion to dismiss where plaintiff's "'overall scheme' claim rests upon determinations that flow from factual allegations"); *Rochester Drug Coop. v. Braintree Labs.*, 712 F. Supp. 2d 308, 318 (D. Del. 2010) ("if [plaintiffs] can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability"); *see also, e.g.*, *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.* ("*In re EpiPen*"), 2017 U.S. Dist. LEXIS 209710, at *63 (D. Kan. Dec. 21, 2017) (denying motion to dismiss where allegations of exclusive dealing and other conduct "taken as a whole" plausibly stated scheme to monopolize).

J&J's attempt to single out and/or mischaracterize parts of Pfizer's Complaint, while never acknowledging its totality, should be rejected, particularly when

it does not challenge the Complaint's detailed allegations concerning J&J's anticompetitive scheme.

### B. Even If Viewed Myopically as a "Bundling" Case, Pfizer's Allegations Are More Than Adequate

Pfizer alleged that, as just one facet of its exclusionary scheme, J&J "bundled" rebates on multiple products, including Remicade, such that insurers and healthcare providers that refused to grant exclusivity to Remicade would be forced to pay higher prices for *other* J&J products. *See supra* pp. 8-9. The Third Circuit has established that this sort of multi-product bundling, when undertaken by a monopolist like J&J, can be anticompetitive. *LePage's*, 324 F.3d at 159. J&J asserts that for an anticompetitive bundling allegation to survive a motion to dismiss, a plaintiff must allege in its complaint an inability to offer a competing bundling discount package of its own. Defs.' Corrected Mem. at 11-16. J&J thus argues that, because Pfizer is a "large[]" company that offers a variety of products, *id*. at 12, it was required to "plead[] facts . . . that demonstrate that it somehow could not offer a bundle drawn from its own broad product line." *Id.* at 13. J&J cites no precedent—and Pfizer is not aware of any case—that supports this position. What precedent does exist is to the contrary.

The court's decision in *SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089 (E.D. Pa. 1976), is particularly instructive. There, the court entered an injunction against pharmaceutical manufacturer Eli Lilly, barring it from pursuing a bundling scheme involving Lilly's substantial line of cephalosporin products, which risked impeding plaintiff SmithKline's ability to compete with its more limited lineup of cephalosporin drugs. *Id.* at 1094, 1104, 1106, 1108. The district court reached this result despite the fact that SmithKline, like Pfizer, was a large pharmaceutical company with a

broad array of products beyond cephalosporin drugs. The court did not inquire into whether SmithKline theoretically could have countered Lilly's anticompetitive bundling with bundles involving non-cephalosporin products. Rather, the court condemned Lilly's program because SmithKline was not able to offer a bundle of *comparable products*. *See id*. at 1121. The Third Circuit affirmed the district court.[4] *SmithKline Corp. v. Eli Lily & Co.*, 575 F.2d 1056, 1065 (3d Cir. 1978).

The facts that Pfizer has pled here unquestionably meet the standard established in *SmithKline*. The Complaint alleges that Pfizer is a single-product producer in respect of the products at issue in J&J's bundle. Based on Pfizer's current understanding, J&J's bundles include the drugs Stelara and Simponi/Simponi Aria (together with Remicade), whereas Pfizer's only product in the relevant product markets is Inflectra. *See, e.g.*, Compl. ¶¶ 67, 84-85. The Complaint also alleges that, to the extent J&J in fact is bundling additional products (using the "full breadth of its portfolio"), J&J has drugs "for which Pfizer does not offer any directly competing alternative."

[4] Several decades after *SmithKline*, the Third Circuit in *LePage's* upheld a jury's verdict that multi-product bundling undertaken by a monopolist was anticompetitive. *LePage's*, 324 F.3d at 155-57. That decision relied heavily on the court's reasoning in *SmithKline*. *See id.* J&J claims that subsequent Third Circuit decisions (*Eisai* and *ZF Meritor*) established that bundling can only be anticompetitive where "a single-product producer is excluded through a bundled rebate program[.]" Defs.' Corrected Mem. at 13. But these cases do not support the sweeping rule J&J advances. As an initial matter, neither *Eisai* nor *ZF Meritor* involved claims of multi-product bundling, and the courts in both cases were discussing *LePage's* largely to distinguish it because it *did* involve such bundling. *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 405-06 (3rd Cir. 2016); *ZF Meritor*, 696 F.3d at 274 n.11. And, most importantly, the court in neither case gave any indication it intended to overrule its holding in *SmithKline*, on which *LePage's* primarily relied.

Compl. ¶ 67; *see also* ¶¶ 13, 46-47, 56 n.17, 65-66, 76, 103-104 (describing Pfizer's efforts to compete against J&J's exclusionary scheme).[5]

Nor do the cases that J&J cites establish any different standard. J&J cites only two bundling cases, but neither case supports its argument. Defs.' Corrected Mem. at 13 (citing *Invacare Corp. v. Respironics, Inc*., 2006 U.S. Dist. LEXIS 77312, at *34-35 (N.D. Ohio Oct. 23, 2006); *Ethicon, Inc.*, 2006 U.S. Dist. LEXIS 12845, at *9). Both *Invacare* and *Ethicon* were decided at the summary judgment stage, and neither dismissed the plaintiff's claims on the pleadings. In fact, both cases support the point that bundling claims proceed where the plaintiff does not have a comparable product to match against the defendants' bundle, which, as discussed above, is the case here.[6]

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[5] Other courts have allowed bundling claims to go forward under similar circumstances. *See*, *e.g.*, *LePage's Inc. v. 3M*, 1997 U.S. Dist. LEXIS 18501, at *20-31 (E.D. Pa. Nov. 14, 1997) (denying defendant's motion to dismiss despite plaintiff not alleging whether it could offer a competing bundle); Second Am. Compl. ¶ 1, *LePage's Inc. v. 3M*, 1998 WL 35428889 (E.D. Pa. Sept. 2, 1998) (even more-detailed second amended complaint lacked allegations regarding an inability to offer competing bundles); *Applied Med. Res. Corp. v. Ethicon Inc.*, 2006 U.S. Dist. LEXIS 12845, at *9-10, 18-20 (C.D. Cal. Feb. 2, 2006) (denying summary judgment, finding jury issue as to whether a competitor's products were dissimilar and thus not competitive against the monopolist's bundle); *Universal Hosp. Servs. v. Hill-Rom Holdings, Inc.*, 2015 U.S. Dist. LEXIS 154154, at *26 (W.D. Tex. Oct. 15, 2015) (denying a motion to dismiss bundling claims where complaint alleged that competition only effective if an upstart competitor could match all products in the challenged bundles); *Masimo Corp. v. Tyco Health Care Grp., L.P.*, 2004 U.S. Dist. LEXIS 26916, at *25-31 (C.D. Cal. June 9, 2004) (denying summary judgment where plaintiff, which was a multiproduct manufacturer, "could not match" defendant's bundles, even though plaintiff had the "capabilities to offer a discount that exceeded [defendant's] rebates").

[6] In *Ethicon*, where J&J was also the defendant, the court *denied* the motion for summary judgment and allowed the plaintiff's bundling claims to proceed to trial. The plaintiff in that case, Tyco, is an enormous multinational company that sells dozens, if not hundreds, of products. Nonetheless, the court found there was at least a fact question as to whether Tyco was "toothless" in its ability to constrain J&J's monopoly power because its products were dissimilar to the products in the monopolist's (J&J's) bundle. *Ethicon*, 2006 U.S. Dist. LEXIS 12845, at *9-10. In *Invacare*, the court dismissed bundling claims at the summary judgment stage because "unlike in *SmithKline* or *LePage's*,

Moreover, Pfizer alleges near-total foreclosure and higher overall prices arising from J&J's scheme, which, as discussed below, more than adequately state antitrust injury. *See infra* Section III.

### C. J&J's Proposal Would Require the Court to Resolve Fact Questions at the Pleading Stage

As noted, J&J invites this Court to rule now that its contracts are examples of price competition, thereby ignoring the well-pled allegations to the contrary in Pfizer's Complaint. And that is not all. To grant J&J's motion, the Court would need to accept the idea that Pfizer can offer effective counter-bundles without record evidence as to the full extent of J&J's bundles, let alone whether Pfizer could match such bundles. To resolve such issues at this stage would be manifestly improper, even if Pfizer had pled a simple "bundling" case. *See supra* n.5; *see also, e.g.*, *In re Hypodermic Prods. Antitrust Litig*., 2007 U.S. Dist. LEXIS 47438, at *35-36 (holding that "particularized allegations" regarding "specific product[s] as the subject of . . . a bundled discount" unnecessary at the pleading stage).

## II. J&J's Contentions Regarding Pfizer's Pricing Do Not Support Dismissal

J&J's second argument for dismissal is also without merit. J&J claims that Pfizer's Complaint should be dismissed because "Pfizer has failed to allege facts showing that it has offered net prices on Inflectra to payors that were lower than

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Plaintiff *manufactures the same products and can match the product bundles* offered by Defendant." 2006 U.S. Dist. LEXIS 77312, at *35 (emphasis added). The court's dismissal was based on the upstart competitor's ability to "match" the monopolist's bundles. J&J ignores that the plaintiff in *Invacare* was able to sell the same products as those in the monopolist's bundle. Indeed, citing a leading treatise on antitrust law, the court in *Invacare* focused on whether the plaintiff could match the defendant's bundle "across all product lines." *Id*. at *36-37. As noted, Pfizer's Complaint alleges that, based on its current knowledge of J&J's bundles, Pfizer is unable to match J&J across the products it is bundling.

Remicade's or facts showing that it has been incapable of doing so." Defs.' Corrected Mem. at 16. As an initial matter, even monopolists who price their products below their competitors are not, as J&J seems to imply, entitled to enter into exclusionary contracts with impunity. *See, e.g.*, *ZF Meritor*, 696 F.3d at 271 ("Exclusive dealing arrangements are of special concern when imposed by a monopolist."). Exclusive dealing contracts—regardless of price—can foreclose markets to competition, and it is "[t]he foreclosure of markets" that "is of concern under the antitrust laws." *See LePage's*, 324 F.3d at 158; *see also infra* Section III (for more authority).

In any event, Pfizer alleges repeatedly and with significant detail that Inflectra's prices were lower, so there is no merit to J&J's claim that Pfizer did not "attempt[] to compete for payor contracts" by offering lower prices. Defs.' Corrected Mem. at 17. Pfizer alleged in its Complaint that (a) through a combination of a lower list price and discounts, rebates, and other price concessions, Pfizer positioned Inflectra to be lower-priced than Remicade unit-for-unit, and (b) because J&J conditioned its pricing on contractual exclusivity, Pfizer could not offset J&J's "all-or-nothing" rebates without pricing Inflectra below its own cost. Such allegations are more than adequate to state a claim.

### A. Pfizer Sufficiently Alleges that Inflectra Is Priced Lower Than Remicade

J&J does not dispute that Inflectra's list price is lower than that of Remicade. Instead, J&J claims that the Complaint improperly focuses only on Inflectra's lower list price, while ignoring the impact of rebates, discounts and other price concessions. Contrary to J&J's assertion, however, the Complaint is replete with allegations that Pfizer positioned Inflectra as the lower-priced infliximab—not only on a

list price, but also on a net price, basis—through rebates, discounts and other price concessions. For example, the Complaint:

- Discusses how "Remicade's ASP was more than 10 percent higher than Inflectra's ASP." Compl. ¶ 13.
- Discusses how Pfizer "committed to ensure that Inflectra would have a lower net per-unit price than Remicade." *Id.* ¶ 46.
- Discusses that Pfizer offered "substantial additional pricing concessions [beyond list price] in the form of discounts and/or rebates[.]" *Id.*
- Notes that Pfizer "has offered Inflectra at a significant discount (to list price as well as ASP)[.]" *Id.* ¶ 56 n.17.
- Discusses the "per-unit cost savings" Pfizer believed it was making available to insurers. *Id*. ¶ 64.
- Alleges that "Pfizer offers a significantly lower price for Inflectra unit-for-unit[.]" *Id.* ¶ 66.
- Notes that "Pfizer was and is prepared to negotiate with providers to make Inflectra the lower-priced infliximab on a per-unit basis, and has even offered to guarantee that Inflectra would be less expensive unit-for-unit than Remicade." *Id*. ¶ 76.
- Explains that Pfizer has offered guarantees that "Inflectra would be less expensive unit-for-unit than Remicade." *Id*. ¶¶ 13, 103.

These allegations plainly refute J&J's claim. Defs.' Corrected Mem. at 3, 7-9, 16.

J&J also asserts that Pfizer does not include allegations that it is prepared to engage in negotiations with insurers (as opposed to providers) to make Inflectra the lower-priced infliximab. Defs.' Corrected Mem. at 16. But, among other allegations, the Complaint makes clear that "in negotiations *with insurers* and providers, [Pfizer] *offered substantial additional pricing concessions* in the form of discounts and/or rebates," and that the "goal and effect" of such negotiations with insurers and providers "was to *offer Inflectra for less than J&J was offering Remicade*." Compl. ¶ 46 (emphasis added).

Moreover, and despite J&J's now-retracted attempt to suggest otherwise, the government-published ASP figures cited in Pfizer's Complaint in fact include rebates and discounts to insurers. As stated in the Complaint, these figures show that (a) Inflectra's ASP has been lower than Remicade's ASP (and decreasing) and (b) not only has Remicade's ASP been higher than Inflectra's, it has been *increasing*. Compl. ¶¶ 13, 81-82, 104, 112. The ASP data only underscores the plausibility of the factual allegations described above.[7]

J&J cites no authority to support its claim that these detailed pricing allegations are somehow insufficient. Indeed, J&J's motion to dismiss does not reference a single pleading-stage dismissal of a claim challenging exclusive (or otherwise anticompetitive) contracting on the ground that the plaintiff did not plead enough detail that its prices were lower than the monopolist's. The only case J&J references, *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, was decided on summary judgment, after a full record had been developed in discovery. Defs.' Corrected Mem. at 18 (citing 2016 U.S. Dist. LEXIS 136478 (C.D. Ill. Sept. 30, 2016)). J&J cites *Methodist Health* for the proposition that Pfizer had an obligation to plead that it was "precluded from competing

[7] The fact that the ASP is an average does not negate its utility at this phase, which is simply to underscore (a) that J&J's conduct here is not causing overall prices to come down (as J&J tries to imply when it refers to its supposed price competition against biosimilars) and (b) that the effect of J&J's conduct is to deny a major savings opportunity to providers, patients, and insurers (including the federal government). Nor does the fact that the then-current ASP is based on trailing data change the story. The published ASP lags the quarter of the sales by at most two quarters and is adjusted for certain price concessions based on prior months. *See* 42 C.F.R. § 414.804(a)(3); Office of Inspector Gen., Dep't of Health and Human Servs., *Average Sales Prices: Manufacturer Reporting and CMS Oversight*, at i (Feb. 2010), available at https://oig.hhs.gov/oei/reports/oei-03-08-00480.pdf. But Inflectra entered the market over one year ago, so at least the two most recently-reported Remicade ASP figures reflect the best publicly available estimate of J&J's post-biosimilar pricing, and Inflectra's ASP figures by definition reflect prices that are post-biosimilar entry.

for the [insurer and provider] contracts at issue." *Id.* But to support this argument, J&J *quotes the defendant's brief*, which was attached to the court's opinion in connection with its unsealing of the defendant's motion for summary judgment. *Methodist Health* does not address pleading standards for antitrust injury at all, and J&J appears to have misquoted the court in error.

By contrast, overwhelming authority supports that to survive a motion to dismiss, a Complaint need not include extensive evidentiary detail. That is because, as the Supreme Court has warned, a plaintiff cannot at the pleading stage be required to provide "detailed factual allegations." *Twombly*, 550 U.S. at 555; *see also, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 254 (3d Cir. 2017) ("precise figures and calculations" not required at pleading stage); *In re Hypodermic Prods. Antitrust Litig.*, 2007 U.S. Dist. LEXIS 47438, at *36 (rejecting defendant's argument that a complaint was deficient for failing to include information on the prices offered in the market, and holding that "no legal authority indicat[es] that such particularized allegations are a pleading requirement").[8] This is particularly true on pricing issues such as those at issue here: at this stage, Pfizer cannot know the detail about J&J's precise net pricing for Remicade (beyond such measures as the publicly-available ASP). The substantial factual detail regarding pricing that Pfizer pled in its Complaint is more than enough to sustain its antitrust claims at the pleading stage—and, as discussed, detail surrounding J&J's

[8] Indeed, J&J does not mention that in *Eisai v. Sanofi*—a case it cites at the summary judgment stage —the district court *denied* a motion to dismiss over defendant's argument that the plaintiff drug manufacturer had not alleged "the prices at which [plaintiff's allegedly disadvantaged drug product] was sold, the discounts [plaintiff] offered, or the reason for [plaintiff's] alleged loss of sales." *Eisai Inc. v. Sanofi-Aventis U.S.*, LLC, No. 3:08-cv-04168 (D.N.J. Oct. 27, 2008), ECF No. 28-1 at p. 22, No. 59, No. 61 at pp. 71-73. The case proceeded to discovery despite plaintiff providing far less detail than Pfizer has here.

prices and discounts (including what it chooses to include in the specific ASP figures it reports to the federal government) are quintessential fact issues inappropriate for resolution at this stage.

### B. Pfizer Amply Alleges How J&J's Scheme Blocks Effective Price Competition from Biosimilar Rivals

Pfizer's Complaint not only amply alleges its efforts to engage in price competition, it also explains how its efforts were blocked by J&J's anticompetitive conduct. The Complaint describes the control that J&J has over a massive universe of "incontestable" legacy patients—the "installed base" of existing Remicade patients who are already stable on Remicade and thus "highly unlikely to switch" to Inflectra. Compl. ¶ 9; *see also supra* pp. 7-8. As the Complaint explains, J&J uses this "incontestable" base by threatening to deny rebates on *all* Remicade prescriptions if *any* infliximab biosimilar prescriptions are reimbursed. *Id.* Thus, "[e]ven if Pfizer offers a significantly lower price for Inflectra unit-for-unit, as it has done, insurers will agree to J&J's exclusive deals to avoid losing rebates on the substantial base of existing Remicade patients who are not likely to switch to Inflectra despite the presence of the lower-priced biosimilar." *Id*. ¶¶ 66; 64 ("In most cases," J&J's all-or-nothing rebate contracts "were the only economically viable option for insurers—as adopting any alternative would require the insurer to incur a substantial penalty (i.e., foregone rebates to existing Remicade patients) that could not be offset by the per-unit cost savings available on the number of patients likely to use the biosimilar, at least in the near term.")

Thus, because of the way that J&J leverages its "incontestable" patient base, it is "cheaper" for many insurers to purchase Remicade exclusively *even though* Inflectra is offered at a lower per-unit price. To the extent that this is the basis from

which J&J argues that Pfizer did not sufficiently allege that it "compete[d] for payor" contracts, that argument is unavailing. As Pfizer alleged in the Complaint, "[f]or Pfizer to make up the J&J rebates/discounts that insurers and providers would lose on their existing Remicade patients, Pfizer would have to price Inflectra below its own average variable costs." *Id.* ¶ 77. A claim that a company "failed to compete" because it did not price products at a loss defies logic, and J&J cites no case so holding.

On the contrary, courts recognize the harm to competition where rivals would be forced to price below cost to match "all-or-nothing" conditional deals imposed by monopolists. *See, e.g.*, *SmithKline*, 427 F. Supp. at 1108 ("When the effect of the rebates SmithKline would have to give . . . in order to compete effectively with Lilly's [rebates] is taken into consideration, *SmithKline's profitability disappears, even if SmithKline were able to reduce its costs of goods to Lilly's levels*.") (emphasis added), *aff'd*, 575 F.2d at 1065 (finding all-or-nothing rebate program forced plaintiff SmithKline "to pay rebates on *one product* . . . equal to rebates paid by Lilly based on volume sales of *three* products" and finding "SmithKline's prospects for continuing in the cephalosporin market under these conditions to be poor"; no requirement stated that SmithKline price below cost to sustain a claim) (emphasis added); *LePage's*, 324 F.3d at 157 (to match monopolist 3M's all-or-nothing rebates, plaintiff LePage's would have had to pay rebates equaling "as much as half of LePage's entire prior tape sales" to particular large customers; no requirement that LePage's do so to maintain a claim); *United States v. Dentsply*, 399 F.3d 181, 195 (3d Cir. 2005) (defendant monopolist's all-or-nothing exclusive arrangements with artificial teeth dealers anticompetitive where "rivals simply could not provide dealers with a comparable economic incentive to switch"); *Castro et al.*

*v. Sanofi Pasteur Inc.*, 134 F. Supp. 3d 820, 832 (D.N.J. 2015) (allowing expert testimony on exclusionary conduct where "overcoming [defendant's] bundle required [plaintiff] Novartis to price below cost").[9]

More broadly, the Third Circuit has made clear that it is anticompetitive for a monopolist to coerce customers into not dealing with rivals where the monopolist uses its dominance to impose exclusionary deals customers cannot refuse. *See, e.g.*, *Dentsply*, 399 F.3d at 195-96 (recognizing that customers faced with an "all-or-nothing choice" imposed by a monopolist "may accede to the dominant firm's wish for exclusive dealing," due to "heavy economic pressure"); *ZF Meritor*, 696 F.3d at 288 (exclusive contracting by monopolist problematic where it "ensured that no rival would be able to offer a comparable deal"); *SmithKline*, 575 F.2d at 1062-68 (affirming district court decision finding that the effect of Lilly's all-or-nothing rebate program was magnified by the volume of Lilly's products sold, so that "in order to offer a rebate of the same new net dollar amounts as Lilly's, *S*mithKline had to offer" substantially larger per-unit rebates for its (lower-volume) product).

[9] *See also, e.g.*, *McWane v. FTC*, 783 F.3d 814, 832 (11th Cir. 2015) ("an exclusive dealing arrangement can be harmful when it allows a monopolist to maintain its monopoly power by raising its rivals' costs sufficiently to prevent them from growing into effective competitors") (citing XI Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1804a, at 116-17 (3d ed. 2008) (describing how exclusive contracts can raise rivals' costs and harm competition)); Steven C. Salop, The Raising Rivals' Cost Foreclosure Paradigm, Conditional Pricing Practices, and the Flawed Incremental Price-Cost Test, 81 Antitrust L.J. 371, 399, 401 (2017) (conditional pricing practices "fundamentally differ from the plain-vanilla price discounts of the predatory pricing paradigm because of the conditions attached to them. . . . [T]he attached conditions . . . can raise rivals' costs and erect barriers to entry. . . . In some cases, the plaintiff's costs might be sufficiently raised and/or its output sufficiently constrained that it would be forced to exit."); Thomas G. Krattenmaker & Steven C. Salop, Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price, 96 Yale L.J. 209 (1986)).

## III. Pfizer Adequately Alleges Antitrust Injury

As detailed above, Pfizer's Complaint alleged that J&J hatched a multifaceted scheme—involving exclusive deals for Remicade, multi-product bundling, and rebates based on the bundling of new and existing patients—to preserve its monopoly. Pfizer further alleged that this scheme has had the effect of substantially foreclosing Inflectra from the relevant market and that the result of Inflectra's foreclosure has been increased prices and decreased consumer choice. *See supra* p. 12. These allegations are sufficient to establish antitrust injury, particularly at the pleading stage.

It is well-established that a competitor suffers antitrust injury when it is foreclosed from a market due to exclusionary dealing arrangements imposed by a monopolist. "When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary . . . conduct, [the monopolist's] success in that goal is not only injurious to the potential competitor but also to competition in general." *LePage's*, 324 F.3d at 154-59, 169 (antitrust injury established, based on exclusive contracts and multi-product bundles); *see also Dentsply*, 399 F.3d at 193 (where monopolist's "aggressive rebate program damaged [a plaintiff competitor's] ability to compete" it thereby "harmed competition itself"); *ZF Meritor*, 696 F.3d at 271 (antitrust injury where "dominant firm . . . able to foreclose rival suppliers from a large enough portion of the market to deprive such rivals of the opportunity to achieve the minimum economies of scale necessary to compete"); *id.* at 281 ("Where, as here, a dominant supplier enters into *de facto* exclusive dealing arrangements with every customer in the market, [competing] firms may be driven out not because they cannot compete on a price basis, but because they are never given an opportunity to compete, despite their ability to offer products with significant customer

demand."); *GN Netcom, Inc. v. Plantronics, Inc.*, 967 F. Supp. 2d 1082, 1086-87 (D. Del. 2013) ("exclusive dealing arrangements can result in antitrust injury by 'allowing one supplier of goods and services unreasonably to deprive other suppliers of a market for their goods'"); *see also, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 70-71 (D.C. Cir. 2001) (agreements by monopolist anticompetitive where they "close[] to rivals a substantial percentage of the available opportunities for . . . distribution").

Pfizer alleged just such injury due to substantial foreclosure in its Complaint. Compl. ¶¶ 8, 10, 12, 59, 72, 79, 100, 102, 127. And Pfizer further alleged facts demonstrating the impact that this foreclosure has had on competition itself—and, thus, patients and payors. As described above, Pfizer alleged that J&J maintained a higher list price and ASP for Remicade than Inflectra was offering, and that by increasing Remicade's list price J&J was able to threaten more severe penalties for insurers that declined to accept its exclusivity conditions. Compl. ¶¶ 13, 55-64. J&J's ability to maintain these higher prices, while preventing Inflectra from gaining any traction in the market, demonstrates the harm that J&J's conduct has caused to competition and consumers alike.[10]

[10] J&J argues that other causal factors may have limited Inflectra's sales, but J&J does not argue those factors are grounds for dismissal. Defs.' Corrected Mem. at 1, 14-15. Nor could it. Pfizer is not required to plead around all alternative explanations for Inflectra's lack of success that J&J may choose to suggest. *See, e.g.*, *Rossi v. Standard Roofing*, 156 F.3d 452, 483 (3d Cir. 1980) ("a plaintiff need not exhaust all possible alternative sources of injury") (quoting *Zenith Radio Corp.* v Hazeltine Research, Inc., 395 U.S. 100, 114 n.9 (1969)); *Van Dyk Research Corp. v. Xerox Corp.*, 631 F.2d 251, 254-55 (3d Cir. 1980) (plaintiff need establish only that the "illegal conduct was a material cause of its injury"); *see also In re EpiPen*, 2017 U.S. Dist. LEXIS 209710, at *76 (denying motion to dismiss and rejecting argument that "alternative reasons caused the alleged injuries"). At most, J&J's speculation raises fact issues that cannot be resolved at this stage.

Just a few weeks ago another district court, considering a case originating from this circuit, denied a motion to dismiss in an MDL proceeding involving an alleged exclusionary contracting scheme similar to J&J's here. *In re EpiPen*, 2017 U.S. Dist. LEXIS 209710. *EpiPen*, like this case, involved antitrust claims asserted by one drug manufacturer (Sanofi) against another (Mylan). Sanofi alleged that Mylan "leveraged its greater than 90% market share [as to the EpiPen epinephrine delivery system] by offering unprecedented rebates to third-party payers . . . but expressly *condition*[*ing*] those rebates on excluding [Sanofi's] Auvi-Q®" product. *Id*. at *38 (emphasis added). Like J&J here, Mylan had attempted to depict Sanofi's case as a challenge to its rebates. The court rejected this argument, holding that Sanofi had sufficiently alleged that Mylan's rebate program "involved exclusionary conduct capable of supporting a finding or inference that the probable effect of Mylan's rebate program—*conditioned on exclusivity*—substantially foreclosed competition." *Id*. at *46-47 (emphasis added); *see also URL Pharma, Inc. v. Reckitt Benckiser, Inc.*, 2015 U.S. Dist. LEXIS 112859, at *22-23 (E.D. Pa. Aug. 25, 2015) (antitrust injury adequately pled when defendant's actions had "deprived [plaintiff] and consumers of the economic benefits of increased supply and a lower-priced product"); *Xerox Corp. v. Media Scis. Int'l, Inc.*, 511 F. Supp. 2d 372, 381-382 (S.D.N.Y. 2007) (competitor's exclusion from the market, resulting in "fewer choices and potentially higher prices . . . is exactly the type [of injury] that antitrust laws were designed to prevent"); *Yeager's Fuel v. Pennsylvania Power & Light Co.*, 953 F. Supp. 617, 660 (E.D. Pa. 1997) (exclusive deals forced consumers to "incur . . . increased costs . . . and forego a less expensive and more efficient" product).

In summary, Pfizer has alleged that J&J used a multifaceted scheme, featuring exclusive dealing contracts and other anticompetitive tactics, to maintain a monopoly, foreclose competition, and charge higher prices. J&J's attempt to argue that a complaint alleging such conduct and effects should be dismissed at the outset is utterly baseless.

## CONCLUSION

For the foregoing reasons, J&J's motion to dismiss should be denied.

Respectfully submitted,

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